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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,242	12/03/2003	Brian D. Kelley	GI5329A	7811

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/728,242	KELLEY ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

2. In the preliminary amendment filed December 03/2003, claims 1-9 have been cancelled, and new claims 10 and 11 have been added. Therefore, claims 10 and 11 are examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 10-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 10 and 11 are directed to a method for purification of a factor VIII polypeptide comprising adding a mixture to an immunoaffinity matrix, eluting factor VIII polypeptide from the immunoaffinity matrix with an elution solution which desorbs the factor VIII polypeptide, wherein the elution solution comprises a low-polarity agent (i.e., non-polar agent) and a buffer, diluting the elution solution about 1.5 fold to 3 fold with a solution comprising a lower concentration of the low-polarity agent than that of the elution solution, passing the diluted factor VIII solution through ion exchange column which binds the factor VIII polypeptide, and eluting

the factor VIII polypeptide from ion exchange column. While the specification indicates that the desorbing substance used is any non-polar agent such as ethylene glycol, dioxane, propylene glycol and polyethylene glycol, or any appropriate low ionic strength, low polarity buffered solution (page 4, lines 19-21), the specification does not specifically define the term "low-polarity agent" or "non-polar agent", where these agent may refer to non-polar or low-polarity organic solvents, e.g., Engler et al. (U. S. Patent 4,312,935) identify methylene chloride, chloroform and carbon tetrachloride as low polarity solvents (column 4, lines 48-50); and Horii et al. (U.S. Patent 4,486,602) identify dioxane, tetrahydrofuran and acetonitrile as polar solvents, and benzene, hexane, chloroform, dichloromethane and ethyl acetate as non-polar solvents (column 5, line 65-column 6, line 1). Since the specification only discloses four cited compounds as "non-polar agent", and there is no clear definition for the terms, one skilled in the art would not know how to identify a low-polarity agent or a non-polar agent from numerous organic materials except for the ones cited in the specification. The lack of description for the term "low-polarity agent" or "non-polar agent", and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 10 and 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-8 of U. S. Patent 6,683,159. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 10 and 11 in the instant application disclose a method for purification of a factor VIII polypeptide comprising adding a mixture to an immunoaffinity matrix, eluting factor VIII polypeptide from the immunoaffinity matrix with an elution solution which desorbs the factor VIII polypeptide, wherein the elution solution comprises a low-polarity agent (i.e., non-polar agent) and a buffer, diluting the elution solution about 1.5 fold to 3 fold with a solution comprising a lower concentration of the low-polarity agent than that of the elution solution, passing the diluted factor VIII solution through ion exchange column which binds the factor VIII polypeptide, and eluting the factor VIII polypeptide from ion exchange column. This is an obvious variation in view of claims 5-8 in the patent which disclose a method for purification of a factor VIII polypeptide comprising adding a mixture to an immunoaffinity matrix, eluting factor VIII polypeptide from the immunoaffinity matrix with an elution solution which desorbs the factor VIII polypeptide, wherein the elution solution comprises a non-polar agent, wherein the non-polar agent comprises at least one of ethylene glycol, dioxane, propylene glycol and polyethylene glycol, diluting the elution solution about 1.5 fold to 3 fold with a solution comprising a lower concentration of the non-polar agent than that of the elution solution, passing

the diluted factor VIII solution through ion exchange column which binds the factor VIII polypeptide, and eluting the factor VIII polypeptide from ion exchange column. Both the claims of instant application and the claims of the patent are directed to a method for purification of a factor VIII polypeptide by eluting the factor VIII polypeptide from an immunoaffinity column and ion exchange column, where the elution solution from the immunoaffinity column is diluted with a solution comprising lower concentration of non-polar agent than that of the elution solution, prior to passing the diluted solution through the ion exchange column. Thus, claims 10 and 11 in present application and claims 5-8 in the patent are obvious variations of a method for purification of a factor VIII polypeptide by eluting the factor VIII polypeptide from an immunoaffinity column and ion exchange column.

5. Claims 10 and 11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-14, 16-27 and 29-36 of co-pending Application No. 11/043,784. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 10 and 11 in the instant application disclose a method for purification of a factor VIII polypeptide comprising adding a mixture to an immunoaffinity matrix, eluting factor VIII polypeptide from the immunoaffinity matrix with an elution solution which desorbs the factor VIII polypeptide, wherein the elution solution comprises a low-polarity agent (i.e., non-polar agent) and a buffer, diluting the elution solution about 1.5 fold to 3 fold with a solution comprising a lower concentration of the low-polarity agent than that of the elution solution, passing the diluted factor VIII solution through ion exchange column which binds the factor VIII polypeptide, and eluting the factor VIII polypeptide from ion exchange column. This is an obvious variation in view of claims 12-14,

16-27 and 29-36 in the patent which disclose a method for purification of a factor VIII polypeptide comprising adding a mixture to an affinity matrix (i.e., composed of monoclonal antibody), eluting factor VIII polypeptide from the affinity matrix with an elution solution which desorbs the factor VIII polypeptide, wherein the elution solution comprises a low-polarity agent or a non-polar agent, wherein the non-polar agent comprises at least one of ethylene glycol, dioxane, propylene glycol and polyethylene glycol, diluting the elution solution about 1.5 fold to 3 fold with a solution comprising a lower concentration of the non-polar agent (or low-polarity agent) than that of the elution solution, passing the diluted factor VIII solution through ion exchange column which binds the factor VIII polypeptide, and eluting the factor VIII polypeptide from ion exchange column. Both the claims of instant application and the claims of the patent are directed to a method for purification of a factor VIII polypeptide by eluting the factor VIII polypeptide from an immunoaffinity column and ion exchange column, where the elution solution from the immunoaffinity column is diluted with a solution comprising lower concentration of non-polar agent than that of the elution solution, prior to passing the diluted solution through the ion exchange column. Thus, claims 10 and 11 in present application and claims 12-14, 16-27 and 29-36 in the co-pending application are obvious variations of a method for purification of a factor VIII polypeptide by eluting the factor VIII polypeptide from an immunoaffinity column and ion exchange column.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

6. No claims are allowed.

Art of Record

Neslund *et al.* (U. S Patent 5,470,954) teach a process for purifying factor VIII:C by immunoaffinity chromatography and ion exchange chromatography, however, the reference does not teach the elution solution from the immunoaffinity column is diluted with a solution comprising higher salt concentration, or lower concentration of low-polarity agent than that of the elution solution, prior to passing the diluted solution through the ion exchange column. Therefore, it appears the claimed method is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.

Patent Examiner

CHIH-MIN KAM
PATENT EXAMINER

CMK

July 8, 2005